

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Patent Application of:  
Yukio ANDO et al.

Application No.: 10/527,597

Confirmation No.: 3475

Filed: March 14, 2005

Art Unit: 1633

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For: PREPARATION FOR FACILITATING SITE-  
SPECIFIC GENE CONVERSION AND  
PREPARATION FOR GENE THERAPY

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Examiner: K. K. Hill

**INFORMATION DISCLOSURE STATEMENT**  
**(SUBMISSION AFTER FILING OF AN APPLICATION BUT BEFORE FINAL**  
**REJECTION OR NOTICE OF ALLOWANCE OR CONCURRENTLY WITH A RULE**  
**1.114 RCE APPLICATION)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications, or other information submitted for consideration by the Office are listed on the PTO-SB08(s), attached hereto.

II. COPIES

- ☒ a. Copies of cited U.S. patents and patent application publications are not included. Copies of foreign patent documents and non-patent literature are included.

☐ b. Some or all of the documents listed on the PTO-SB08 are not enclosed because they were cited in the International Search Report and copies should already be in the PTO file. If copies are needed, please contact the undersigned.

☐ c. REFERENCES PREVIOUSLY CITED OR SUBMITTED - Pursuant to 37 C.F.R. §1.98(d), consideration of information listed on the PTO-SB08 form(s) is requested since any patents, publications, or other information which are listed on the PTO-SB08 form(s) but for which copies are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

U.S. Appl. No(s) and U.S. Filing Date

III. CONCISE EXPLANATION OF THE RELEVANCE

(check at least one box)

☒ a. DOCUMENTS IN THE ENGLISH LANGUAGE - The patents, publications, or other information listed on the attached PTO SB08 are in the English language and therefore, do not require a statement of relevancy.

☒ b. DOCUMENTS NOT IN THE ENGLISH LANGUAGE - A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows:

Reference Cite No. AA, US 2004/0052840 corresponds to WO 01/97857.

☒ c. ENGLISH LANGUAGE SEARCH REPORT - An English language version of the search report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(III)(A)(3).

☒ d. OTHER - The following additional information is provided for the Examiner's consideration.

**Only abstracts have been made available to Applicants' Representative for references CF, CG, CH, CM, CN and CO. The Examiner is invited to obtain complete copies of these items from the USPTO Scientific and Technical Information Center.**

IV. FEES (check one box)

☐ a. This Information Disclosure Statement is being filed concurrently with the filing of a new patent application; therefore, no fee is required.

☐ b. This Information Disclosure Statement is being filed concurrent with the filing of a continuation-in-part, continuation, or divisional patent application; therefore, no fee is required.

☐ c. This Information Disclosure Statement is being filed within three months of the filing date of a national application (37 C.F.R. § 1.97(b)(1)). No fee or statement is required.  
*(This section is not to be used with RCE's.)*

☐ d. This Information Disclosure Statement is being filed within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or statement is required.

☐ e. This Information Disclosure Statement is being filed concurrently with the filing of a Request for Continued Examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.

☒ f. **This Information Disclosure Statement is being filed before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or statement is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the statement under 37 C.F.R. § 1.97(e) below, or, if no statement has been made, charge our deposit account for the fee as required by 37 C.F.R. § 1.17(p).**

☐ g. This Information Disclosure Statement is being filed before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c)(1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c)(2)).

☐ No statement; therefore, a fee as required by 37 C.F.R. § 1.17(p) is attached.  
or

☐ See the statement below. No fee is required.

V. STATEMENT UNDER 37 C.F.R. § 1.97(e)

(check only one box)

The undersigned hereby states that:

☐ a. Each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than 30 days prior to the filing of this IDS; or

☐ b. Each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ c. No item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the IDS.

☐ d. Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was first cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application and, to the best of my knowledge after making reasonable

inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

VI. PAYMENT OF FEES (check one box)

☐ The required fee is listed on the attached Fee Transmittal.

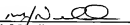
☒ No fee is required.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 02-2448.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: March 13, 2007

Respectfully submitted,

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Attachment(s):

- ☒ PTO-SB08
- ☒ Documents
- ☒ Foreign Search Report
- ☐ Fee

Substitute for form 1449/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				Application Number	10/527,597-Conf. #3475
				Filing Date	March 14, 2005
				First Named Inventor	Yukio ANDO
				Art Unit	1633
				Examiner Name	K. K. Hill
Sheet	1	of	1	Attorney Docket Number	5094-0101PUS1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA*	US-20040052840-A1	03-18-2004	Kubota et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> -Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>4</sup>
	BA	WO-01/97857-A1	12-27-2001			Abs

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 608. Draw line through citation if not in conformance and not considered. Include copy of the form with next communication to applicant. <sup>1</sup> CITE NO.: Those application(s) which are marked with an single asterisk (\*) next to the Cite No. are not supplied (under 37 CFR 1.809(k)(2)(ii)) because that application was filed after June 30, 2003 or is available in the IPW. <sup>2</sup> Applicant's unique citation designation number (optional). <sup>3</sup> See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 801.04. <sup>4</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>5</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>6</sup> Kind of document by the appropriate symbol as indicated on the document under WIPO Standard ST.16 if possible. <sup>7</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
	CA	NAKAMURA et al., "Gene therapy of familial amyloidotic polyneuropathy (FAP) by RNA/DNA chimera oligonucleotides and single-stranded oligonucleotides", Sagawa Sentan Kagaku Gijutsu Shinko Zaidan Josei Kankyu Hokokusho, Volume date 2001, 14th, pp. 29-34, 9 September 2002			
	CB	WELZ et al., International Journal of Pharmaceutics, Vol. 196, 2000, pp. 251-252			
	CC	HARTIG et al., Biology of the Cell, September 1998, Vol. 90, No. 5, pp. 407-426			
	CD	CONNORS et al., Amyloid: International Journal of Experimental and Clinical Investigation, March 2000, Vol. 7, No. 1, pp. 54-69			
	CE	PALACIOS et al., Amyloid: International Journal of Experimental and Clinical Investigation, December 1999, Vol. 6, No. 4, pp. 289-291			
	CF	UENO et al., Abstract of Biochemical and Biophysical Research Communications, 1990, Vol. 169, No. 1, pp. 143-147			Abs
	CG	UENO et al., Abstract of Brain, 1992, Vol. 115, No. 5, pp. 1275-1289			Abs
	CH	SAKASHITA et al., Abstract of Virchows Archiv, April 2000, Vol. 436, No. 4, pp. 345-350			Abs
	CI	GERMAIN, Rev. Med Interne, December 2000, Vol. 21, No. 12, pp. 1086-1103, English translation of Abstract			Abs
	CJ	ANDO, Rinsho Byori (Japanese Journal of Clinical Pathology), 2003, Vol. 51, pp. 530-535, English translation of Abstract			Abs
	CK	ANDO, Amyloid: J. Protein Folding Disord., August 2003, Vol. 10, Suppl. 1, pp. 55-66			
	CL	NAKAMURA et al., Gene Therapy, May 2004, Vol. 11, No. 10, pp. 838-846			
	CM	NAKAMURA et al., Abstract of Rinsho Byori (The Japanese Journal of Clinical Pathology), October 2004, Vol. 52, No. 10, pp. 804-812			Abs
	CN	SUHR et al., Abstract of Liver Transplantation, Vol. 10, No. 12, pp. 1551-1553			Abs
	CO	NAKAMURA et al., Abstract of Expert Opinion on Biological Therapy, Vol. 4, No. 10, pp. 1621-1627			Abs

Examiner Signature	Date Considered
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